REMARKS

Claims 1, 2, 12-15, 17, 23-27, 29-37 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 12, 23, 32, and 35 have been amended, claim 28 has been cancelled, and claim 37 has been added. Applicant believes that the claim amendments, cancellation, addition, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicant respectfully submits that that they do not limit the range of any permissible equivalents.

Interview Summary

A telephonic interview was held with the Examiner on April 12, 2004 to discuss and clarify proposed amendments to the claims. Applicant reviewed proposed claim amendments, which are the claim amendments presented herein, and identified the specification support for the proposed amendments and differentiation from the prior art cited in the Office Action.

Additionally, Applicant sought to clarify the election of species 5, FIG. 6. In the Restriction Requirement the Examiner provided a list of distinct species, species 1-11. Figure 7 was not included in the species listing. Applicant submitted to the Examiner that FIG. 7 is included in the election of species 5, support for which is found in the specification. The stent 26A of Fig. 7 has the same configuration as stent 26 shown in Fig. 6, except that the thickness of the structure varies. Specification, p. 8, lns. 16-18.

Drawing Objection

The Examiner objected to the drawing under 37 CFR 1.83(a) stating the drawings must show every feature of the invention specified in the claims. Therefore, the coating layers must be shown or the feature(s) cancelled from the claims. Accordingly, Applicant submits herewith proposed new FIG. 14 showing the two coating layers. The content of FIG. 14 is supported in the specification, for example at page 9, lines 26. No new matter has been added.

Accordingly, Applicant requests reconsideration and withdrawal of the objection to the drawings.

In the Specification

The specification has been amended to correct spelling errors. No new matter has been added.

Additionally, the specification has been amended to reference proposed new FIG. 14 and associated item numbers. Specifically, on page 7, line 26 a new paragraph has been added to provide a brief description of FIG. 14. Additionally, the paragraph beginning on page 9, line 26 has been amended to reference FIG. 14 and to include item numbers for the two coating layers. No new matter has been added.

Claim Rejections – 35 USC §112

Claims 2, 25, and 32 were rejected under 35 USC 112, first paragraph. Specifically, the Examiner asserts:

> The specification does not provide any definition for the recitations "closed cell" and "open cell." Although the drawings provide some examples for "closed cells" and "open cells", there is no definition for the recitations. For one ordinary skill in the art, a cell is conventionally considered as a redial opening and the struts that enclosed the opening. Without any definition in the specification, it is not possible to appreciate what is covered by the recitation "open cells."

Applicant submits that the terms "closed cell" and "open cell" are terms of art that a person of ordinary skill in the art would readily understand and appreciate what is covered by the recitation of "closed cell" and "open cell." Specifically, an open cell stent is defined as a stent that has circumferential sets of strut members with most of the curved sections that are not connected by a longitudinal connecting link to an adjacent circumferential set of struts. A closed cell stent has every curved section of every circumferential set of strut members, except at the distal and proximal end of the stent, attached to a longitudinal connecting link. The definitions of "open cell" and "closed cell" are provided, for example, in U.S. Patent No. 6,540,774, to Fischell et al, entitled Ultraflexible Open Cell Stent.

In light of the foregoing, Applicant submits that claims 2, 25, and 32 satisfy the requirements of 35 USC 112, first paragraph, and respectfully requests reconsideration and

withdrawal of the rejections.

Claim Rejections – 35 USC §102 -Penn

Claims 23-26 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,375,677 to Penn *et al.* ("Penn").

Penn discloses a stent comprising a tubular wall 25 disposed between proximal end 15 and distal end 20. (Col. 8, ln. 14). The porosity of tubular wall 25 is defined by a plurality of intersecting members 30. (Col. 8, lns. 17-18). Intersecting members 30 define a first repeating pattern designated A in FIG. 1. (Col. 8, lns. 18-20). As disclosed the provision of first repeating pattern A, as illustrated, necessarily defines and provides for a second repeating pattern B. (Col. 8, lns. 39-41). It is further disclosed that the second repeating pattern B is a mirror image of first repeating pattern A taken along an axis (not shown) substantially normal to longitudinal axis 45. (Col. 8, lns. 42-45). A preferred embodiment of Penn involves combining various of the repeating patterns illustrated in FIGS. 2-10 to achieve a stent with relatively flexible and rigid regions. (Col. 11, lns. 51-54).

Penn discloses that, the coating may be disposed on the interior and/or the exterior surface(s) of the stent. (Col. 7, lns 9-11). The coating material can be one or more of a biologically inert material (e.g. to reduce the thrombogenicity of the stent), a medicinal composition which leaches into the wall of the body passageway after implantation (e.g. to provide anticoagulant action, to deliver a pharmaceutical to the body passageway and the like) and the like. (Col. 7, lns 11-16).

The Examiner states that as to claims 23, 25, and 26, Penn (Figs. 3 and 12a-12i) shows a stent having every limitation as recited in the claims such as one pattern at both ends and another different pattern in the mid section, linear struts between patterns, the mid section includes articulations 270. As to claim 24, PENN (Figs. 12a-12i) shows some undulating members of the stent.

In contrast and as disclosed in the specification, it is preferred to have two layers of coatings on the entire length of the stent 26. Specification, p. 9, ln. 26 –p. 10, ln. 1. The amount of drug loaded on the stent is varied along with the rel ase characteristics. Specification, p. 6, lns.

4-6. Since restenosis occurs in a stent invariably at its ends, a higher drug concentration at the ends can more thoroughly inhibit such restenosis. Specification, p. 9, lns. 19-21.

In order to clarify the present invention, claim 23 now recites that "the base structure coated by at least two layers having a depth not exceeding ten microns, wherein one of the layers including a drug inhibiting restenosis, with the drug concentration varying along the longitudinal length." Support for this amendment can be found in the specification at, for example, page 9 lines 19-21.

Applicant submits that Penn does not disclose each and every element as set forth in amended claim 23, either expressly or inherently. For example, Penn does not disclose the surface coating includes a drug inhibiting restenosis. Additionally, Penn does not disclose the drug having a higher concentration at the first and second end portions than at the mid portion. As such, Penn does not expressly disclose a surface coating includes drug inhibiting restenosis, nor the drug having a higher concentration at the first and second end portions than at the mid portion.

In light of the foregoing, amended independent claim 23 is respectfully submitted to be patentable over Penn. As claims 24-26 depend from claim 23 and necessarily include all the elements of their base claim, Applicant respectfully submits that these dependent claims are also allowable over Penn at least for the same reasons.

Claim Rejections – 35 USC §103 –Penn in view of Callol

Claims 1, 2, 13-15, 28, 29, 31, 32, 34 and 36 were rejected under 35 U.S.C. § 103(a) as unpatentable over Penn in view of U.S. Patent No. 6,174,329 to Callol *et al.* ("Callol"). The Examiner states that as to claims 1, 2, 14, 28, 29, 31, 32, 34, and 36, Penn discloses substantially all the limitations in the claims, except for two layers of coating not more than 10 microns. Callol (claim 1 and 4) discloses a stent having an inner coating layer of a thickness from 0.01 to 25 microns and an outer coating layers for thickness from 1.0-50 microns.

Callol discloses a stent intended for either temporary or permanent deployment in a body lumen such as a coronary artery, carotid artery, vessels in the brain, aorta, peripheral arteries and veins, and the like. The stent also can be deployed in the urethra and other body lumens. (Col. 3,

lns. 7-10). In order to increase the visibility of stent 10, radiopaque layer 14 is applied to coat all of stent 10, including outer surface 12 and inner surface 13. (Col. 4, lns. 54-56). It is preferred that radiopaque layer 14 have a uniform thickness in the range of 1.0 to 50 microns, and more preferably in the range of from 1.5 to 10 microns. (Col. 4, lns. 62-65). In keeping with the preferred embodiment, as shown in FIGS. 1-3, protective layer 20 covers and surrounds radiopaque layer 14 and protects it against scratches, flaking, and other mishandling. (Col. 5, lns. 5-7).

In the preferred embodiment shown in FIGS. 4-6, stent 10 is coated by protective layer 34 which actually covers stent portion 31 and partial radiopaque layer 30. (Col. 5, lns. 41-43). Protective layer 34 protects partial radiopaque layer 30 as described above, and it eliminates the possibility of galvanic corrosion when stent 10 and partial radiopaque layer 30 are dissimilar metals. (Col. 5, lns. 43-47).

The radiopaque coating can be made from solid metal (i.e., gold, silver, tin, tantalum, zirconium, platinum, or other metals), ceramic (Zirconia, alumina, zirconium nitrate, titanium nitrite, graphite, pyrolytic carbon, Nedox, or other ceramics), metal/ceramic-filled particles dispersed in a polymer matrix, or other radiopaque material. (Col. 5, lns. 55-60). In the preferred method of applying protective layer 30, 34, the biocompatible and blood-compatible protective layer can be polymeric, Parylast, polymethylene, metallic, or ceramic. (Col. 6, lns. 24-27).

As such Callol discloses a stent have a radiopaque layer applied thereto to increase the visibility of the stent. A protective layer is included to protect the radiopaque layer from damage. Alternatively, the protective layer is applied between the stent and the radiopaque layer to prevent galvanic corrosion between the stent and the radiopaque layer.

In contrast, as noted above, and as disclosed in the specification, it is preferred to have two layers of coatings on the entire length of the stent 26. Specification, p. 9, ln. 26 – p. 10, ln. 1. Because of the variable thickness of the stents, the amount of drug loaded on the stent is varied along with the release characteristics. Specification, p. 6, lns. 4-6. Since restenosis occurs in a stent invariably at its ends, a higher drug concentration at the ends can more thoroughly inhibit such restenosis. Specification, p. 9, lns. 19-21.

In order to clarify the present invention, claim 1 now recites that "wherein one of the layers including a drug inhibiting restenosis, with the drug concentration varying along the longitudinal length." Support for this amendment can be found in the specification at, for example, page 9 lines 19-21.

As noted above, Penn does not disclose the surface coating includes a drug inhibiting restenosis. Additionally, Penn does not disclose the drug having a concentration varying along the longitudinal length.

The combination of Callol does not relieve the deficiencies in Penn. Specifically, Callol discloses a stent have a radiopaque layer and a protective layer applied thereto to increase the visibility of the stent. There is no disclosure in Callol of a drug for inhibiting restenosis. Additionally, there is no disclosure of the concentration of the drug varying along the longitudinal length of the stent.

As such, the combination of Penn and Callol does not expressly disclose a surface coating includes drug inhibiting restenosis, nor the drug having a higher concentration at the first and second end portions than at the mid portion.

Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. As noted above, Penn in view of Callol do not teach or suggest all of the claim elements. Additionally, there is no motivation or suggestion to modify the reference. Callol teaches coatings to increase the visibility of the stent. As such, there is no motivation or suggestion to modify Penn such that the one of the layers including a drug inhibiting restenosis, with the drug concentration varying along the longitudinal length.

In light of the foregoing, amended independent claim 1 is respectfully submitted to be patentable over Penn. As claims 2 and 13-15 depend from claim 1 and necessarily include all the elements of their base claim, Applicant respectfully submits that these dependent claims are also allowable over Penn in view of Callol at least for the same reasons.

With regard to claims 28, 29, and 31, claim 28 has been cancelled rendering the rejection to this claim moot. Claims 29 and 31 have been amended to depend from claim 23. As noted above claim 23 is submitted to be patentable of Penn. The inclusion of Callol does not remedy the d ficiencies noted in Penn. As claims 29 and 31 depend from claim 23 and necessarily include

all the elements of their base claim, Applicant respectfully submits that these dependent claims are also allowable over Penn in view of Callol at least for the same reasons.

Additionally, Penn discloses the stent is coated as follows:

> The non-expanded stent may be placed in a tube having a slightly larger diameter than the stent. The tube may then be filled with coating solution and the solution allowed to drain steadily from the tube to form a completely coated stent. Immediately thereafter a stream of warm air or nitrogen may be directed through the tube at a linear velocity of 0.1.5 m/s at room temperature to 50.degrec. C. for a period of 30 seconds to 5 minutes to dry the coating by evaporation of the ethanol solvent.

As such, the method of coating the Penn stent necessarily provides a uniform coating on the stent.

Callol discloses it is preferred that radiopaque layer 14 have a uniform thickness. (Col. 4, lns. 62-65). Alternatively, as seen in FIGS. 4-6 stent 10 is only partially coated by partial radiopaque layer 30. (Col. 5, lns. 21-23). Portions of stent 10 are coated with partial radiopaque layer 30, while stent portion 31, which is curved, is not covered by a radiopaque layer. (Col. 5, lns. 23-25). It is preferred that partial radiopaque layer 30 be applied to the non-curved structure of the stent. (Col. 5, lns. 34-35). Stent 10 is coated by protective layer 34 which actually covers stent portion 31 and partial radiopaque layer 30. (Col. 5, lns. 41-43).

As such, Callol discloses a stent having a partial radiopaque coating on the non-curved sections and having no radiopaque coating on the curved section. The protective layer coats both the partial radiopaque coating, on the non-curved sections, the non coated portions of the stent. There is not disclosure in Callol that the thickness of the partial radiopaque coating or the protective coating is greater at the end potions of the stent.

In contrast and as disclosed in the specification, the stent of the present invention can include two coating layers having a thickness greater at the two end portions then at the mid portion. Specifically, if the coating is to enhance the radio opacity, then the ends can be made more radiopaque than the mid-portion. Specification, p. 9, lns. 15-17. If the objective of a coating is to load more drugs then the ends of the stent can be thicker to allow for such coating. Specification, p. 9, lns. 17-19.

In order to clarify the present invention, claim 32 now recites "wherein the at least two layers have a thickness greater on the first and second end portions than on the mid portion." Support for this amendment can be found in the specification at, for example, page 9 lines 15-19.

As noted above, Penn does not disclose the surface coating having a thickness greater on the end portions then on the mid portion. The combination of Callol does not relieve the deficiencies in Penn. Specifically, Callol disclose a partial radiopaque coating, coating only the non curved section of the stent. Callol does not disclosure that the coating on the end portions of the stent have a greater thickness then the mid-portion of the stent. The combination of Penn and Callol does not expressly disclose a surface coating having at least two layers and a thickness greater on the first and second end portions than on the mid portion.

As such, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. As noted above, Penn in view of Callol do not teach or suggest all of the claim elements. Additionally, there is no motivation or suggestion to modify the reference.

In light of the foregoing, amended independent claim 32 is respectfully submitted to be patentable over Penn in view of Callol. As claims 34 and 36 depend from claim 32 and necessarily include all the elements of their base claim, Applicant respectfully submits that these dependent claims are also allowable over Penn in view of Callol at least for the same reasons.

Withdrawn claims

The Examiner withdrew claims 12, 17, 27, 30, and 33 from further consideration, as being drawn to non-elected species 11.

Initially, claim 12 has been amended to read on Figure 7, namely, the at least two layers varying in thickness. Additionally, Applicant submits that claims 17, 27, 30 and 33 are not drawn to non-elected species 11, but to Figure 7. As noted above, Applicant elected species 5, FIG. 6. In the Restriction Requirement the Examiner provided a list of distinct species, which included species 1-11. Figure 7 was not included in the species listing. Applicant submits FIG. 7 is included in the election of species 5, support for which is found in the specification.

Accordingly, Applicant respectfully request reconsideration of the withdrawal of claims 12, 17, 27, 30, and 33.

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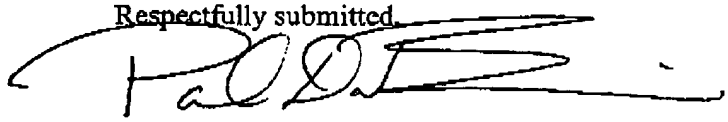
Application No.: 09/941,327
Examiner: V. Bui

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 795-A02-006).

Respectfully submitted,



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